

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shaker A. Mousa

Group Art Unit: 1623

Application No.: 10/667,216

Examiner: Lau, Jonathan S.

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Docket No.: **MOUSA-4618**

Title: **OXIDIZED HEPARIN FRACTIONS AND THEIR USE IN INHIBITING
ANGIOGENESIS**

Commissioner for Patents
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**REQUEST FOR REHEARING FOLLOWING
DECISION ON APPEAL, UNDER 37 CFR § 41.52**

This request for rehearing, under 37 CFR § 41.52, follows the Decision on Appeal issued by the Board of Patent Appeals and Interferences (hereinafter, “Board”) on September 29, 2010.

Appellant respectfully contends that the Board’s Decision on Appeal (“Decision”) has misapprehended or overlooked important points as discussed *infra*.

Ground of Rejection 2: Claim 1 (Anticipation By Naggi)

1. Chemical Structure

Claim 1 recites the following chemical structure: “wherein the super-sulfated oxidized heparin fraction has a chemical structure of a first oxidized heparin fraction after the first oxidized heparin fraction has been O-sulfated by sulfate substitution at oxygen bonds within repeating units of the first oxidized heparin fraction”.

The Decision, page 11, with respect to rejection of claim 1 as anticipated by Naggi, recites: “Naggi's heparin fraction is obtained by treating a starting heparin with a mixture of sulfuric acid and chlorosulfonic acid, known oxidizing agents, to produce supersulfated heparin fractions having a molecular weight between 2 and 9 kDa, e.g., the 3to 5 kDa molecular weight Naggi heparin fraction of Example 2 (FF 5-6). Neither the instant Specification nor the claims require using specific oxidizing agents to oxidize starting heparin materials or performing oxidation and sulfation in any particular order (see e.g., FF 1-3)”.

The preceding text on page 11 of the Decision makes the assertion that a mixture of sulfuric acid and chlorosulfonic acid oxidizes Naggi's heparin fractions, which is a ***misapprehension*** because Naggi does not expressly or inherently teach this assertion.

Naggi does not expressly teach that a mixture of sulfuric acid and chlorosulfonic acid oxidizes Naggi's heparin fractions, which the Examiner and the Board do not dispute

Instead, the Board alleges that Naggi inherently teaches that a mixture of sulfuric acid and chlorosulfonic acid oxidizes Naggi's heparin fractions, which is not demonstrated by the preceding text on page 11 of the Decision. Appellant respectfully disputes the Board's reliance (for proving the alleged inherency) on: (i) sulfuric acid and chlorosulfonic acid being known oxidizing agents; and (ii) Finding of Fact (FF) 1-3 on page 7 of the Decision.

Appellant's reply brief, pages 3-4, provides citations demonstrating that an alleged inherency must **necessarily and inevitably** flow from teachings in the prior art as a matter of law.

The Board argument that sulfuric acid and chlorosulfonic acid are known oxidizing agents is not pertinent, because sulfuric acid and chlorosulfonic acid are not known to oxidize every existing substance on Earth. Neither sulfuric acid nor chlorosulfonic acid nor any other reactant is capable of oxidizing every existing substance on Earth. It is well known to a person of ordinary skill in the art of chemistry that a reactant is an oxidizing agent only for those substances that the reactant is capable of oxidizing. Thus, the fact that a given reactant can oxidize some substances does not imply that the given reactant will oxidize other substances. Therefore, any allegation that a given reactant (e.g., sulfuric acid, chlorosulfonic acid) oxidizes a specified substance (e.g., heparin, heparin fractions) must be proved by scientific evidence.

In particular, the Examiner's Answer has not demonstrated, via scientific evidence, that the alleged inherency of a mixture of sulfuric acid and chlorosulfonic acid oxidizing Naggi's heparin fractions **necessarily and inevitably** flows from teachings in the prior art and thus does not comply with the existing legal standard for proving inherency. The Examiner's Answer is legally required to provide scientific evidence to prove the alleged inherency that a mixture of sulfuric acid and chlorosulfonic acid oxidizes heparin or heparin fractions, which the Examiner has not provided. The Board's failure to require the Examiner to provide scientific evidence allegedly proving that a mixture of sulfuric acid and chlorosulfonic acid oxidizes heparin or heparin fractions is a *misapprehension* by the Board that Appellant is respectfully alleging.

The Board relies on Finding of Fact (FF) 1-3 of the Decision to support the Board's allegation that "Neither the instant Specification nor the claims require using specific oxidizing agents to oxidize starting heparin materials or performing oxidation and sulfation in any

particular order”. Of particular relevance is the Board’s Finding of Fact B [1] on page 7 of the Decision which recites: “According to the instant Specification, oxidizing agents "including, but not limited to, periodic acid, metals in high valence states, halogens, halogen atoms, and compounds with O-O bonds, such as O₃, diacyl peroxides, H₂O₂, and O₂" may be used to oxidize heparin fractions (Spec. 8, ¶ 26).”

In response, as explained in detail on pages 5-7 of Appellant’s reply brief, the aforementioned "including, but not limited to" language in Appellant’s specification merely states that there may be other oxidizing agents that could be used for oxidizing heparin fractions according to the present invention, but does not teach that any oxidizing agent could be so used. Furthermore, the Examiner has not even proven that a mixture of sulfuric acid and chlorosulfonic acid necessarily and inevitably oxidizes heparin or heparin fractions as explained *supra*. Therefore, Appellant respectfully contends that the Board’s reliance on FF 1-3 to support the alleged inherency of a mixture of sulfuric acid and chlorosulfonic acid oxidizing heparin or heparin fractions is a *misapprehension*.

In any event, Appellant would like to know what evidence demonstrates **necessarily and inevitably** that a mixture of sulfuric acid and chlorosulfonic acid oxidizes heparin or heparin fraction. Appellant has searched the pertinent scientific literature extensively for such evidence and cannot find such evidence. Appellant has consulted with heparin chemists who assert that sulfuric acid and chlorosulfonic acid do not oxidize heparin. Clearly, all that is known is that a mixture of sulfuric acid and chlorosulfonic acid depolymerizes and supersulfates heparin (Naggi, col. 5, lines 47-51). ***EVIDENCE TO ESTABLISH THE ALLEGED INHERENCY APPARENTLY DOES NOT EXIST. THE BOARD HAS ALLOWED THE EXAMINER TO ESTABLISH THE ALLEGED INHERENCY VIA PURE SPECULATION BY EXEMPTING***

THE EXAMINER FROM HAVING TO PRESENT SCIENTIFIC EVIDENCE TO ESTABLISH THE ALLEGED INHERENCY.

In summary, Appellant respectfully contend that the Board has *misapprehended* the legal requirement that the Examiner must provide scientific evidence to prove the alleged inherency that a mixture of sulfuric acid and chlorosulfonic acid **necessarily and inevitably** oxidizes heparin or heparin fractions.

Since Naggi does not inherently teach that a mixture of sulfuric acid and chlorosulfonic acid oxidizes heparin or heparin fraction, Naggi's chemical structure of supersulfated heparin fractions differ from Appellant's claimed chemical structure of supersulfated heparin fractions.

2. Full Inhibition of Angiogenesis

Claim 1 recites the following structural feature: "wherein the super-sulfated oxidized heparin fraction has a chemical structure of a first oxidized heparin fraction after the first oxidized heparin fraction has been O-sulfated by sulfate substitution at oxygen bonds within repeating units of the first oxidized heparin fraction".

Claim 1 recites the following functional characteristic: "wherein the super-sulfated oxidized heparin fraction fully inhibits fibroblast growth factor (FGF2) induced angiogenesis"

The Decision, page 12, with respect to rejection of claim 1 as anticipated by Naggi, argues that the claimed functional characteristic (i.e., full inhibition of angiogenesis) is an inherent characteristic of the claimed structural feature. The Decision, pages 11- 12 argues that the burden has shifted to Appellant to demonstrate that the claimed functional characteristic is not an inherent characteristic of the claimed structural feature, alleging that "the Examiner has provided a sufficient factual basis for reasonably believing that Naggi's heparin fraction and the claimed heparin fraction ***are the same or substantially the same*** compound (emphasis added)".

To support the preceding argument regarding shifting of the burden of proof, the Decision cites *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430 (CCPA 1977).

In response, Appellant respectfully contends that the Board *misapprehends* the prevailing legal standard for shifting the burden to Appellant to rebut the alleged inherency, because the prevailing legal standard is not that Naggi's heparin fraction and the claimed heparin fraction are *the same or substantially the same* compound” (emphasis added).

In re Best, 195 USPQ at 433 recites the legal standard as: “the claimed and prior art products are *identical or substantially identical*” (emphasis added).

In re Spada, 15 USPQ2d at 1658 recites the legal standard as: “*virtual identity*” (emphasis added).

Since *In re Spada* (1990) is later in time than *In re Best* (1977), Appellant asserts that legal standard in *In re Spada* of “virtual identity” over-rules *In re Best* and currently prevails for the instant appeal. Appellant respectfully contends that “virtual identity” is a *more stringent* standard for shifting the burden to Appellant to disprove the alleged inherency than is “the same or substantially the same”.

Therefore, the Board *misapprehended* the prevailing legal standard to use for determining that the burden has shifted to Appellant to demonstrate that the claimed functional characteristic is not an inherent characteristic of the claimed structural feature.

Since Appellant has demonstrated *supra* that Naggi does not inherently teach that a mixture of sulfuric acid and chlorosulfonic acid oxidizes heparin or heparin fraction, Naggi's chemical structure differs from Appellant's claimed chemical structure of supersulfated heparin fractions. Therefore, the Board's analysis has not met the “virtual identity” standard for shifting

the burden to Appellant to show that Naggi's chemical structure does not fully inhibit angiogenesis.

In addition, the Decision, page 12 argues: "The fairness of shifting the burden of proof to the Appellant at this point is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best*, 562 F.2d at 1255."

In response, Appellant asserts that Appellant is an individual with limited resources who does not have the ability to manufacture products or to obtain and compare prior art products. Consequently, the criteria for fairness cited by the Board ("inability to manufacture products or to obtain and compare prior art products") is ***a reason not to shift the burden of proof*** to Appellant, especially since the Examiner has the burden of proof to begin with.

Thus, by applying the criteria for fairness for the benefit of the PTO and not applying the criteria for fairness for the benefit of Appellant, the Board has ***misapprehended*** how the doctrine of fairness expressed in *In re Best* should be applied to the claims of the present patent application.

In addition, the Board ***overlooked*** an argument made by Appellant regarding claim interpretation that effectively traverses the Examiner's argument that the claimed functional characteristic (i.e., full inhibition of angiogenesis) is an inherent characteristic of the claimed structural feature.

In particular, Appellant's appeal brief, page 20 (last sentence) recites: "The scope of claim 1 does not include all super-sulfated oxidized heparin fractions that may potentially exist, but is specifically limited to those super-sulfated oxidized heparin fractions that fully inhibit FGF2 induced angiogenesis." which the Board has ***overlooked***.

Appellant respectfully contends that the pertinent issue in the previously quoted last sentence on page 20 of Appellant's appeal brief is whether the claimed functional characteristic recited in claim 1 should be interpreted:

(i) as a limitation that further limits the claimed structural feature to fewer super-sulfated oxidized heparin fraction than is recited in the claimed structural feature; OR

(ii) as an inherent consequence of the claimed structural feature and therefore does not further limit the claimed structural feature to fewer super-sulfated oxidized heparin fraction than is recited in the claimed structural feature.

Interpretation (i) is equivalent to the claimed structural feature being a necessary but not sufficient condition for the claimed functional characteristic to be satisfied.

Interpretation (ii) is equivalent to the claimed structural feature being a necessary and sufficient condition for the claimed functional characteristic to be satisfied, which is a prerequisite for inherency to be relevant.

Appellant respectfully contends that the language of claim 1 supports Appellant's interpretation (i) as Appellant has explicitly argued (i.e., "The scope of claim 1 does not include all super-sulfated oxidized heparin fractions that may potentially exist, but is specifically limited to those super-sulfated oxidized heparin fractions that fully inhibit FGF2 induced angiogenesis"), because claim 1 explicitly expresses the claimed functional characteristic as a limitation via the recited "wherein" clause. There is no language recited in claim 1 which expresses the claimed structural feature as a necessary and sufficient condition for the claimed functional characteristic to be satisfied

Thus if the scope of claim 1 does not include all super-sulfated oxidized heparin fractions that may potentially exist, but is specifically limited to those super-sulfated oxidized heparin

fractions that fully inhibit FGF2 induced angiogenesis, then mere conformity to the claimed structural feature is not sufficient to infer satisfaction of the claimed functional characteristic, because the scope of structures conforming to the claimed structural feature is broader than the scope of structures that are further limited by the claimed functional characteristic. Thus the claimed functional characteristic cannot be an inherent consequence of the claimed structural feature.

Furthermore, it is unreasonable to assume that any structure satisfying the claimed structural feature would inherently satisfy the claimed functional characteristic, because: (i) the scope of the claimed functional characteristic includes millions of chemical structures which defines *a very broad range* of super-sulfated oxidized heparin fractions, and (ii) the claimed functional characteristic of *full inhibition* of angiogenesis is *very narrow characteristic*. A person of ordinary skill in the art of pharmacy and angiogenesis inhibition would not consider it possible for the millions of chemical structures with the scope of the claimed chemical structure to necessarily and inevitably impart the claimed functional characteristic (of full inhibition of angiogenesis) to each and every structure of said millions of chemical structures.

Thus, by *overlooking* Appellant's argument of "The scope of claim 1 does not include all super-sulfated oxidized heparin fractions that may potentially exist, but is specifically limited to those super-sulfated oxidized heparin fractions that fully inhibit FGF2 induced angiogenesis", the Board has unfairly biased the Board's basis for deciding the appeal for the alleged anticipation of claim 1 by Naggi.

In summary, Appellant asserts that the burden of proof as to whether or not the chemical structures of Naggi's supersulfated heparin fractions have the claimed functional characteristic (i.e., full inhibition of angiogenesis) should not be shifted to Appellant, because:

i) the chemical structure of Naggi's supersulfated heparin fractions are not virtually identical to the chemical structure of the supersulfated heparin fractions recited in claim 1, because Naggi does not expressly or inherently teach that a mixture of sulfuric acid and chlorosulfonic acid oxidizes heparin or heparin fractions;

ii) it is unfair to shift the burden of proof to Appellant; because Appellant is an individual with limited resources who does not have the ability to manufacture products or to obtain and compare prior art products, especially since the Examiner has the burden of proof to begin with; or

iii) the claimed functional characteristic (i.e., full inhibition of angiogenesis) should be interpreted as a limitation that further limits the claimed structural feature to fewer supersulfated oxidized heparin fractions than is recited in the claimed structural feature, so that the claimed structural feature is a necessary but not sufficient condition for the claimed functional characteristic to be satisfied, which removes inherency of the claimed functional characteristic as an issue..

Ground of Rejection 2: Claims 93, 2, 5, and 6 (Anticipation By Naggi)

The Decision, pages 12-13 argue that it is fair as to the claimed characteristics specific to claims 93, 2, 5, and 6, citing *In re Best*, 562 F.2d at 1255 as in the Board's analysis of claim 1 with respect to alleged anticipation by Naggi.

In response, Appellant asserts, as in Appellant's analysis of claim 1 with respect to alleged anticipation by Naggi, that the burden of proof as to whether or not the claimed characteristics specific to claims 93, 2, 5, and 6 should not be shifted to Appellant, because of the following considerations which reflect points that the Board misapprehended or overlooked:

i) the chemical structure of Naggi's supersulfated heparin fractions are not virtually identical to the chemical structure of the supersulfated heparin fractions recited in claim 1, because Naggi does not expressly or inherently teach that a mixture of sulfuric acid and chlorosulfonic acid oxidizes heparin or heparin fractions;

ii) it is unfair to shift the burden of proof to Appellant; because Appellant is an individual with limited resources who does not have the ability to manufacture products or to obtain and compare prior art products, especially since the Examiner has the burden of proof to begin with; or

iii) the claimed characteristics specific to claims 93, 2, 5, and 6 should be interpreted as limitations that further limit the claimed structural feature to fewer super-sulfated oxidized heparin fractions than is recited in the claimed structural feature in claim 1, so that the claimed structural feature is a necessary but not sufficient condition for the claimed characteristics specific to claims 93, 2, 5, and 6 to be satisfied, which removes inherency of the claimed characteristics specific to claims 93, 2, 5, and 6 as an issue.

Ground of Rejection 2: Claim 94 (Anticipation By Naggi)

Claim 94 recites: “forming the oxidized heparin fraction of claim 1, wherein said forming the oxidized heparin fraction comprises O-sulfating the first oxidized heparin fraction by performing sulfate substitution at oxygen bonds within repeating units of the first oxidized heparin fraction”.

The Decision, page 15 argues: “As to claim 94, the Examiner has provided a reasoned basis for believing that the recited intermediate structures were inherent in the method described for producing Naggi's heparin fractions (see Ans. 6).

In response, Appellant notes that the Board is referring to the following argument in the Examiner's Answer, page 6: “Naggi et al. discloses the heparin treated with sulfuric acid and chlorosulfonic acid, a strong oxidizing agent, to depolymerize and super-sulfate heparin (example 12 at column 12, lines 1-30), which necessarily encompasses the reaction sequence comprising the steps of oxidizing said heparin in order to depolymerize said heparin and then performing sulfate substitution at oxygen bonds within repeating units of said oxidized depolymerized heparin to produce the super-sulfated heparin of formula IV, meeting the instant limitations of instant claim 94.”

Appellant respectfully contends that the Board is under a *misapprehension* that the preceding argument by the Examiner that Naggi teaches treating heparin with sulfuric acid and chlorosulfonic acid to depolymerize and super-sulfate heparin inherently teaches “O-sulfating the first oxidized heparin fraction by performing sulfate substitution at oxygen bonds within repeating units of the first oxidized heparin fraction”. Naggi teaches only O-sulfating sites on the original heparin. The Examiner's Answer has not provided scientific evidence to prove the Examiner's alleged inherency as explained *supra* in conjunction with claim 1.

Furthermore, the Board is under the *misapprehension* stated in the Examiner's Answer, page 6 that Naggi discloses sulfuric acid and chlorosulfonic acid to be a strong oxidizing agent. Appellant asserts that Naggi does not disclose sulfuric acid and chlorosulfonic acid to be a strong oxidizing agent.

The Decision, page 15 argues: "As to claim 94, ... Regardless, it is well settled that the patentability of a product-by-process claim is based on the product itself. *In re Stephens*, 345 F.2d at 1023."

In response, Appellant respectfully contends that the Board is under a *misapprehension* that claim 94 is a product-by-process claim.

Appellant asserts that claim 94 is not a product-by-process claim, but rather is a method claim performing the step of: "forming the oxidized heparin fraction of claim 1, wherein said forming the oxidized heparin fraction comprises O-sulfating the first oxidized heparin fraction by performing sulfate".

The Decision, page 15 argues: "As to claim 94, ... Furthermore, Appellant has not alleged unexpected results or properties based on preparing the claimed heparin product by a specific series of method steps, e.g., first oxidizing an unfractionated heparin and then enriching with sulfate groups. Rather, the instant Specification is quite clear that oxidation and sulfation may occur in either order (FF 2). Therefore, this argument is not persuasive of patentability."

In response, Appellant respectfully contends that the Board is under a *misapprehension* that the disclosure in the specification that oxidation and sulfation may occur in either order prohibits Appellant from limiting claim 94 to perform oxidation before sulfation.

Appellant respectfully contends that it is a *misapprehension* by the Board to there is no patentable significance to claiming performing the oxidation before performing the sulfation. Performing the oxidation before or after performing the sulfation are alternative embodiments of the invention, and there is patentable significance to claiming either alternative embodiment individually.

Ground of Rejections 3-6: 35 U.S.C. § 103(a)

The Decision, page 20 recites: “Appellant does not contest the Examiner's fact finding in regard to Weitz, Conrad, Kerbel, or Scholander. According to Appellant, the patentability of claims 49-54, 56-59, 61, and 62, stand or fall with the patentability of claim 1 or 43, from which they depend. Claims 1 and 43 are not *anticipated* by Naggi for the reasons given above.”

(Emphasis added)

In response, Appellant asserts that the patentability of claims 49-54, 56-59, 61, and 62, stand or fall with the patentability of claim 1 or 43 *under 35 U.S.C. § 103(a)*, from which they depend. Appellant also notes that claim 43 is a linking claim that depends from claim 1.

However, Appellant respectfully contends that the Board is under the *misapprehension* that the Examiner’s Answer has established a *prima facie* case of obviousness for claim 1, which the Examiner’s Answer has not done, as indicated by the Board’s misdirected reliance on the arguments regarding the alleged *anticipation* of claim 1 by Naggi.

In particular, the arguments in the Examiner’s Answer depends strongly on the following two alleged inherencies for rejecting claim 1 under anticipation by Naggi:

(i) the alleged inherency of a mixture of sulfuric acid and chlorosulfonic acid oxidizing heparin or heparin fractions; and

(ii) the alleged inherency of the chemical structure of Naggi’s supersulfated heparin fractions fully inhibiting angiogenesis.

The element that must be established for inherency under *35 U.S.C. § 102(b) (i.e., anticipation)* is that the alleged inherency exists, which was extensively discussed by the Examiner, Appellant, and the Board.

For inherency *under 35 U.S.C. § 103(a)*, however, an additional element is required to establish inherency, namely that the inherency must be known. Specifically, inherency cannot

be used to reject a claim under 35 U.S.C. § 103(a) if the inherency is unknown in the prior art. *In re Shetty*, 566 F.2d 81, 86, 195 U.S.P.Q. 753, 756-57 (C.C.P.A. 1977) (reversing the Board's rejection of a claim based on alleged inherency under 35 U.S.C. 103 of a method to curb appetite, and stating: "[t]he inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. ***Obviousness cannot be predicated on what is unknown***").

Appellant asserts that the Examiner's Answer has not only failed to provide evidence that the two preceding alleged inherencies are known in the prior art, but failed even to address the issue of whether the two preceding alleged inherencies are known in the prior art. Thus, the Examiner's Answer failed to establish a ***prima facie*** case of obviousness in relation to claim 1.

Under 35 U.S.C. § 103(a), Appellant is obligated to rebut the Examiner's argument in response to a ***prima facie*** case established by the Examiner, and Appellant has done so with respect to all aspects of claim 1 except the issue of whether the two preceding alleged inherencies are known in the prior art. Since the Examiner did not establish a ***prima facie*** case of obviousness for claim 1 with respect to the issue of whether the preceding alleged inherencies are known in the prior art, Appellant had nothing to respond to for this issue.

Accordingly, Appellant respectfully contends that the Board ***misapprehended*** the patent laws for establishing inherency under 35 U.S.C. § 103(a) by not recognizing that inherency cannot be used to reject a claim under 35 U.S.C. § 103(a) if the inherency is unknown in the prior art.

In addition, the Board ***overlooked*** a significant argument that Appellant made with respect to the rejections of claim 1 under 35 U.S.C. § 103(a). Specifically for the rejections of claim 1 under 35 U.S.C. § 103(a), Appellant's appeal brief states reliance on Appellant's

arguments, in Appellant's discussion of the alleged anticipation of claim 1 by Naggi, as to why Naggi does not teach *or suggest* all of the features of claim 1. Appellant's arguments for claim 1 include in Appellant's appeal brief, page 21, a discussion of why full inhibition of FGF2 induced angiogenesis is an *unexpected result*, which is an indicia of unobviousness.

However, both the Examiner's Answer and the Board *overlooked* Appellant's argument explaining why full inhibition of FGF2 induced angiogenesis is an unexpected result, so that the Board did not take this argument into account in deciding whether claim 1 is obvious over the cited prior art under 35 U.S.C. § 103(a).

Conclusion

Based on the preceding arguments, Appellant respectfully requests a rehearing with respect to the rejection of claims 1, 2, 5-6, 43, 40-54, 56-59, 61-63 and 91-94 relative to the decision on appeal issued by the Board of Patent Appeals and Interferences on September 29, 2010.

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